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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,593	08/25/2000	Sarita Chaudhary	9369-151/MG	4599

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/645,593

Applicant(s)

CHAUDHARY ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed on 19 February 2003.
2. The Draftsman has approved the drawings submitted 19 February 2003, and figures 5-8 and 10-13 that were originally filed.
3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 1-23 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 20 November 2002. Applicant's arguments filed 19 February 2003 have been fully considered but they are not persuasive.

Applicant argues that Applicants were the first to isolate the promoter having the sequence shown in SEQ ID NO: 8 and that one of skill in the art would readily isolate or prepare modifications to the sequence and that Applicants have isolated four flax seed-specific promoters which is a representative number of species to demonstrate that

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Applicants are entitled to the scope of claim as currently pending (paragraph spanning pages 9-10 of the Remarks). This argument is not found to be persuasive because the instant specification only describes the claimed genus of seed-preferred promoters obtained from flax based on function and a possible method of isolation, Applicant does not describe any special technical feature of a flax seed-preferred promoter that would adequately describe the claimed genus or the genus of promoters required to practice the claimed method. See MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Applicant argues that claims 1-13 relate to methods for the expression of a nucleic acid sequence of interest in flax seeds using a seed-specific promoter obtained from flax as well as flax plants and flax seeds prepared by the method. Applicant also argues that Applicants have illustrated the effectiveness of the method of their invention through using four different flax seeds promoter and that the description of four different promoters in the method of the invention is sufficient to indicate that Applicants have possession of the claimed invention (page 10, 3rd paragraph of the Remarks). This argument is not found to be persuasive for the reason given above as directed to the

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description of the genus of seed-specific promoters obtained from flax that would be required to practice the claimed method and make the claimed flax plant and seeds.

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at 1021, where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

6. Claims 1-23 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule comprising a nucleic acid sequence comprising bases 1-2040 of SEQ ID NO: 8 having seed-preferred promoter activity, does not reasonably provide enablement for a nucleic acid homologue, a nucleic acid analog or an isolated nucleic acid molecule that hybridizes under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 8, compositions comprising same or method of using same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 20 November 2002. Applicant's arguments filed 19 February 2003 have been fully considered but they are not persuasive.

Applicant argues that the requirement of enablement (of a) disclosure does not mean that the applicant must describe all actual embodiments (page 11, 3rd paragraph of the Remarks). This argument is not found to be persuasive because while the scope

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of enablement must only bear a "reasonable correlation" to the scope of the claims, *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) also teaches that in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.". In the instant case, the predictability of isolating a seed-specific promoter sequence from any plant, or even just a flax plant, is not highly predictable, neither is modification of a known promoter sequence to comprise substitutions, deletions or nucleotide analogs as asserted by Applicant (see page 10-12 of the specification).

Applicant argues that there exists in the art to which the invention pertains a well recognized correlation between the similarity in chemical structure of nucleic acid molecules and the ability of nucleic acid molecules to hybridize under stringent conditions and the similarity in chemical structure of nucleic acid molecules and the degree of homology between nucleic acid molecules...etc (paragraph spanning pages 11-12 of the Remarks). This argument is not found to be persuasive because the issue is not correlating the ability of exemplified nucleic acid molecules to hybridize to other nucleic acids but the issue is that Applicant has failed to adequately teach one of skill in the art how to make and use any seed-preferred promoter obtained from flax or how to make and use analogs, "homologs" and/or hybridizing nucleic acid molecules to that of

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SEQ ID NO: 8. Applicant does not teach what special technical features of SEQ ID NO: 8 relate to seed-preferred expression, to the promoter activity of said sequence or how to modify SEQ ID NO: 8 and retain both seed-preferred activity and promoter activity.

Applicant argues that the "certain instances" cited by the Examiner in the previous Office action represent the exception rather than the rule (paragraph spanning pages 12-13 of the Remarks). This argument is not found to be persuasive, the "certain instances" cited by the Examiner are directed to teaching the unpredictability of the art, and that a reduction to practice is typically required by one of skill in the art to identify critical features of a plant promoter sequence, especially a tissue preferred promoter sequence, and that mere random modifications of a promoter sequence does not enable one of skill in the art to make and use such a modified promoter sequence.

Applicant argues that claims 1-4, 6-10, 12 and 13 are directed to methods for the expression of a nucleic acid sequence of interest in flax seeds using a seed-specific promoter obtained from flax and the resultant flax plants and seeds. Applicant argues that 4 different seed-specific promoters isolated from flax are disclosed and the application teaches a person of ordinary skill in the art how to readily obtain additional seed specific promoters and use such flax seed specific promoters in accordance with the present invention. Applicant additionally argues that Applicant is entitled to claim a method for the expression of a nucleic acid sequence using any flax seed specific promoter in flax seeds (page 13, 3rd paragraph of the Remarks). This argument is not found persuasive because Applicant has failed to adequately teach how to make and

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use the genus of seed-preferred promoters obtained from flax required to practice the method as broadly claimed.

7. Claims 2, 3, 5, 11, 14 and 15 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 20 November 2002. Applicant's arguments filed 19 February 2003 have been fully considered but they are not persuasive.

At claims 2 and 3, Applicant argues that claims 2 and 3 are meant to specify that the seed-specific promoter confers a characteristic that it would normally confer on its native sequence to the nucleic acid sequence of interest (page 14, 2nd paragraph of the Remarks). This argument is not found to be persuasive because the metes and bounds of "expression characteristic" is unclear.

Claims 5, 11, 14 and 15 remain indefinite. Applicant argues that in conjunction with the precise definition of each of the rejected terms as set forth in the specification from page 10, line 28 to page 12, line 25 these terms will be readily understood by the skilled artisan (page 14, 4th paragraph of the Remarks). This argument is not found to be persuasive because it remains unclear what the metes and bounds of the qualitative term "homology" are. In addition, "hybridizes...under stringent hybridization conditions" remains unclear given Applicant's teachings on page 11, 2nd paragraph of the specification that only teaches general interpretations of stringency conditions and does not teach the metes and bounds of the instant claims.

Claim Rejections - 35 USC § 102

8. Claims 1-3, 5-9 and 11-23 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Jain *et al* (WO 98/18948, published 7 May 1998). This rejection is repeated for the reason of record as set forth in the last Office action mailed 20 November 2002. Applicant's arguments filed 19 February 2003 have been fully considered but they are not persuasive.

Applicant argues that the SAD promoters disclosed in Jain *et al* are capable of directing the expression of heterologous nucleic acid sequences in seed, significant expression is observed in other tissues as well (page 15 of the Remarks). Applicant also argues that Jain clearly does not enable the production of seed-specific expression of a nucleic acid of interest (spanning pages 15-16 of the Remarks). This argument is not found to be persuasive because Jain discloses that in transgenic tobacco seeds that leaf expression of the heterologous nucleic acid sequence was insignificant and that both the SAD1 and SAD2 promoters were clearly seed-preferred (see Figure 8). In transgenic flax seed the expression of the heterologous nucleic acid sequence was found to be preferentially expressed in the seed using the SAD1 promoter (see figure 6). Even Applicant recognizes that variations in expression can be due to position effects (page 34, lines 12-14 of the specification). Applicant's own evidence as directed to a transformed flax seed using the legume-like storage protein promoter sequence of SEQ ID NO: 8 showed expression of the heterologous nucleic acid sequence in buds as well as seed (page 34, 1st paragraph of the specification).

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Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
14 May 2003

AMY J. NELSON, PH.D.
SUPERVISORY PATENT EXAMINER
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